

REMARKS

Claims 19 and 25 are being amended to add the phrase "wherein said veterinary pharmaceutical composition is well-tolerated by said mammal" to indicate that the veterinary pharmaceutical composition do not harm the mammal to which it is administered. Support for this amendment is found in the fourth paragraph on page 13 of the Specification.

35 U.S.C. § 103(a)

The Examiner rejected Claims 8 and 19-35 under 35 U.S.C. § 103(a) as being unpatentable over Andoh et al. (U.S. Patent 6,239,077). The Examiner used factors set forth in Graham v John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) in support of this rejection. The Examiner concluded that it would have been *prima facie* obvious to one of ordinary skill in the art to be in possession of the instant compounds and compositions and method of use absent a showing of unexpected results and/or properties.

Enclosed is a Declaration by Dr. Ronald Kaminsky, the head of parasitology group at Novartis Animal Health Inc., an affiliate of the assignee of the present application. In this Declaration (attached as Exhibit A), Dr. Kaminsky states that he has reviewed the present patent application, Andoh et al. (U.S. Patent 6,239,077), and the present Office Action. According to Dr. Kaminsky, Andoh et al. teaches compounds which kill pests that destroy plants and the use of those compounds to kill pests that destroy plants. Dr. Kaminsky states that Andoh et al. does not teach compositions for veterinary use and fails to teach that the Andoh et al. compounds could be used in animals. Dr. Kaminsky states that one of ordinary skill in the field could not predict that the compounds in Andoh et al. could be used to kill external or internal parasites on/in warm-blooded animals because Andoh et al. lacks any teachings that the Andoh et al. compounds could be used on or in mammals. According to Dr. Kaminsky, one of ordinary skill in the art could not know without first conducting tests that veterinary compositions containing the Andoh et al. compounds would be effective at killing internal and external parasites but would not harm the mammal. Dr. Kaminsky found the results disclosed in the present patent application surprising and unexpected.

Dr. Kaminsky's Declaration supports the Applicants' position that the Examiner was incorrect in rejecting the pending claims as being *prima facie* obvious to one of ordinary skill in the art in light of Andoh et al.

The Applicants believe that Andoh et al. merely serves as a basis for experimenting with veterinary compositions that contain the Andoh et al. compounds. Without conducting the experiments, one of ordinary skill in the art would not have known that one could formulate and use the Andoh et al. compounds in such a manner as to kill internal and external parasites that

live on or in mammals without harming the mammal itself. After all, prior to experimenting, one would not know how to formulate and administer the compounds such that the mammals are not harmed but that the external and internal pests are killed. It is possible that one could administer the compositions in too high of a concentration, thereby causing the mammal to die or have an adverse reaction to the compounds. Alternatively, it is possible that one could administer the compositions in too low of a concentration, thereby not killing the pests that live in or on the mammal.

The Examiner acknowledges that Andoh et al. is silent on the application of the compositions on mammals. The Examiner further states that there is nothing of record to show that the compositions taught by Andoh et al. are toxic or cause adverse reactions when administered to mammals. Yet the Examiner then continues by stating that “[s]ince the reference teaches an agricultural use for the composition, one of ordinary skill would have a reasonable expectation of success employing Andoh et al., well-diluted composition on mammals, barring a showing of adverse reaction on mammals when the composition is administered.”

The Applicants respectfully suggest that the Examiner reconsider this argument in light of the DDT, dichloro-diphenyl-trichloro-ethane. DDT is an example of a highly effective agricultural pesticide. However, DDT also is highly toxic to birds, amphibians, fish, and mammals. Just because one could apply DDT to plants to kill plant pests, it is known now that one would not want to apply it, dilute or not, to mammals to killing internal or external parasites on or in the mammal. It was only with much experimenting and use did people skilled in the art realize the extremely hazardous effects of DDT (and much debating about the effects occurred).

Organophosphates and carbamates are two more classes of agricultural pesticides that are not safe for use in mammals. Humans with mild exposure to organophosphates and carbamates can have headache, fatigue, dizziness, loss, of appetite with nausea and stomach cramps, blurred vision (tearing and shrinking of the size of the pupils), sweating, slobbering, vomiting, diarrhea, slowed heart beat, and muscle rippling. Moderate exposure to humans with these types of compounds can result in dilated pupils and secretions from the eyes, nose, mouth, lungs, and skin to unconsciousness and seizures. Because of the toxic effects of these compounds, they are not administered to warm-blooded mammals as pesticides to kill internal or external parasites.

A fourth group of agricultural pesticides that are not used in mammals include paraquat and diquat which are bipyridyls. Exposure to paraquat and diquat can adversely affect skin, nails, mucous membranes, gastro-intestinal tract, and respiratory system. Ingestion of these compounds can result in damage to lungs, kidneys, and liver. Death can occur. As such, one of

ordinary skill in the art would know that bipyridyls cannot be safely administered to mammals to kill internal and/or external parasites.

While the Andoh et al. compounds are not in the same class of compounds as DDT, organophosphates, carbamates, and bipyridyls, the Applicants believe that the Examiner is incorrect in his argument that the claimed compositions and methods are obvious in light of Andoh et al. In light of the history of effective agricultural pesticides being extremely toxic to animals, one of ordinary skill in the art would not expect the Andoh et al. compounds (and compositions containing those compounds) to be safe and effective when applied to mammals. One of ordinary skill simply could not know without conducting experiments that the Andoh et al. compounds (and compositions containing those compounds) could be administered to mammals without harming the mammals but still kill the parasites that live on or in the mammal. Dr. Kaminsky, in his Declaration, believes that such a result is surprising and unexpected.

The Applicants believe that the Examiner has rejected the claims based on the facts known today, not based on the information known to the inventors at the time of making the invention. Especially for Claims 19-30 which cover the method of treating a mammal that lives on or in the mammal and the method of controlling a parasite that lives on or in a mammal, one could not know prior to conducting experiments that the compositions would be safe for the mammal but toxic to the parasite living on or in the mammal. Based on the history of compounds that are effective agricultural pesticides but which are also toxic to mammals, one of ordinary skill in the art could not know prior to conducting experiments that the compositions claimed were safe for the mammals receiving the compositions.

As such, the Applicants respectfully request that the Examiner withdraw the rejection of Claims 8 and 19-35 and allow the pending claims.

In view of the foregoing discussion, Applicants believe that Applicants have overcome the Examiner's rejections. Applicants kindly request that the Examiner withdraw the rejections and allow the claims.

If a telephone interview would be of assistance in advancing the prosecution of this application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below with the goal of agreeing on allowable subject matter.

The Commissioner is authorized to deduct any other fee necessary to keep this application pending, from Deposit Account 19-0134.

Respectfully submitted,

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